

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

REGENTS OF THE UNIVERSITY OF
MINNESOTA,

Plaintiff,

v.

GILEAD SCIENCES, INC.,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Regents of the University of Minnesota (“the University” or “Plaintiff”) makes and files this Complaint for Patent Infringement against Defendant Gilead Sciences, Inc. (“Gilead” or “Defendant”). In support of this Complaint, the University alleges as follows:

THE PARTIES

1. The University is a leading public institution of higher education and advanced research created by charter and perpetuated by the Constitution of the State of Minnesota, Article XIII, Section 3. The University’s main offices are located in Minneapolis, Minnesota.

2. Gilead Sciences, Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

NATURE OF THE ACTION

3. Gilead has infringed, and continues to infringe, the University's intellectual property rights by, among other things, selling medicines containing the drug sofosbuvir, including brand name drugs Sovaldi®, Harvoni®, and Epclusa®. Patent rights assigned to the University by Dr. Carston R. Wagner, Endowed Chair in Medicinal Chemistry in the University's College of Pharmacy, cover Gilead's drugs, and Gilead has reaped tens of billions of dollars in sales of those drugs, without the University's authorization and without compensating the University. The University invests heavily in the important and groundbreaking work of its professors, and it takes seriously its role in defending their and the University's intellectual property rights.

4. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

JURISDICTION AND VENUE

5. As the University asserts claims for patent infringement against Gilead arising under the patent laws of the United States, Title 35, of the United States Code, this Court has jurisdiction over the subject matter of this action under at least 28 U.S.C. §§ 1331 and 1338.

6. Venue in this Court is proper under at least 28 U.S.C. §§ 1391 and 1400.

7. This Court has personal jurisdiction over Gilead.

8. Gilead has substantial and continuous contacts with this judicial district, in that Gilead has conducted business continuously and systematically in the State of Minnesota and this judicial district and continues to conduct that business actively today.

9. For example, within this judicial district, Gilead sells medicines, including the brand name drugs Sovaldi®, Harvoni®, and Epclusa®, each of which contains sofosbuvir.

10. Gilead's sale of medicines containing sofosbuvir infringe U.S. Patent Number 8,815,830 ("the '830 patent").

BACKGROUND

University of Minnesota

11. The University has a long history of research, innovation, and discovery; teaching and learning; and outreach and public service.

12. One of the University's missions is to generate and preserve knowledge, understanding, and creativity by conducting high-quality research, scholarship, and artistic activity that benefit students, scholars, and communities across Minnesota, the nation, and the world.

13. It is also one of the University's missions to extend, apply, and exchange knowledge between the University and society by making the knowledge and resources created and preserved at the University accessible to the citizens of Minnesota, the nation, and the world.

14. The University, which includes eighteen different colleges, supports and facilitates fundamental and applied research in numerous fields.

15. The University faculty number approximately 4,000 and are members of, among other bodies, the National Academy of Sciences, the National Academy of Engineering, the Academy of Medicine, and the American Academy of Arts and Sciences.

16. Much University research, like the scientific and technical research that led to the patent-at-issue in this case, requires significant funding, and thus much of the research performed at the University is financed by various public and private sources.

17. The knowledge obtained through the University's research benefits many people and organizations around the world, including educators, researchers, employers, employees, and consumers. To maximize those benefits, the University sometimes patents and/or commercializes inventions made by researchers at the University, and then returns a portion of the proceeds of those activities to fund further education and research at the University.

18. Over the past 15 years, the United States Patent and Trademark Office ("USPTO") has awarded hundreds of patents to the University, thereby recognizing the many discoveries made by its faculty and staff. These patents span numerous fields and disciplines. Many of these patents are based on groundbreaking research done in the University's College of Pharmacy.

The University's College of Pharmacy

19. The University's College of Pharmacy was founded in 1892 and is the only pharmacy school in Minnesota.

20. The College of Pharmacy is one of the University's preeminent colleges. Since its founding, the College of Pharmacy has been a national leader in education, practice, and policy. The College of Pharmacy consistently ranks among the top pharmacy schools in the nation.

21. The College of Pharmacy offers Doctor of Pharmacy (Pharm.D.), Doctor of Philosophy (Ph.D.) and Master of Science (M.S.) programs, and houses some of the nation's top researchers and brightest students.

22. The faculty at the College of Pharmacy number more than 100 full-time members and hundreds of volunteers.

23. The College of Pharmacy's faculty and students conduct research and clinical activities focused on, *inter alia*, drug discovery and development, pharmaceuticals and drug delivery, experimental and clinical pharmacology, and cancer therapies.

24. One of the professors at the University's College of Pharmacy is Carston R. Wagner, Ph.D. ("Professor Wagner"), the sole named inventor on the patent at issue.

Professor Wagner

25. Professor Wagner has been a professor of medicinal chemistry in the College of Pharmacy since 1991. Since 2010, he has been the Endowed Chair in Medicinal Chemistry in the University's College of Pharmacy.

26. Professor Wagner is a leader in the field of antiviral therapies, and he is a national and internationally recognized expert in phosphoramidate chemistry. For example: from 2003-2014, Professor Wagner was an associate editor for the American Chemical Society's *Molecular Pharmaceutics*, and since 2015, he has been an executive editor for that journal; from 2001 to present, Professor Wagner has been a member of the International Nucleoside, Nucleotide and Nucleic Acid Society; in 2004, he was a member of the program committee for the 17th International Round Table on Nucleosides, Nucleotides, and Nucleic Acids; in 2007, he was the keynote speaker at the 17th International Conference on Phosphorous Chemistry; and in 2015, he served as

National Meeting Theme Chair for the 250th American Chemical Society National Meeting, “Innovation: From Discovery to Application.”

27. Professor Wagner has been working on phosphoramidate chemistry and enzymatic activity in cells, to develop antiviral treatments, for more than twenty years.

28. Professor Wagner has written or co-authored hundreds of published journal and conference papers, about one third of which relate to phosphoramidate chemistry and/or enzymatic activity in cells.

29. Professor Wagner has received numerous industry and academic achievement awards. In 1980, he was named a Dreyfus Undergraduate Research Scholar at the University of North Carolina. In 1986, he was named the National Science Foundation Fellow to the North Atlantic Treaty Organization Advanced Study Institute. For his research from 1987 to 1990, he was awarded the National Institutes of Health (“NIH”) National Research Service Award. In 1993, he received the NIH First Award. In 2002, he received the 3M University Relations Award. In 2012, he received the University’s College of Pharmacy Excellence in Graduate Education Faculty Award. In 2012, he was named an American Association for the Advancement of Science Fellow.

30. Professor Wagner has also advised dozens of students, who have gone on to hold prestigious and influential positions in both academia and industry, and he has been awarded millions of dollars in sponsored research funding, for example, the grants that helped support the antiviral therapy research that led to the patent at issue

31. Professor Wagner researches and designs therapeutic nucleotide prodrugs that can be targeted to and activated by diseased tissues. He also investigates and uncovers the natural functions of proteins, e.g., histidine triad nucleotide-binding proteins (or “HINTs”), so that knowledge of such functions can be applied to designing antiviral medications.

The '830 Patent¹

32. On August 26, 2014, the USPTO duly and lawfully issued the '830 patent, entitled “Nucleosides with Antiviral and Anticancer Activity,” to Dr. Carston R. Wagner. A true and correct copy of the '830 patent is attached hereto as Exhibit A.

33. All rights, title, and interest in and to the '830 patent have been assigned to the University, which is the sole owner of the '830 patent.

34. The '830 patent is directed to antiviral compounds and methods for using those compounds to treat viral infections, such as that caused by hepatitis C virus (“HCV”).

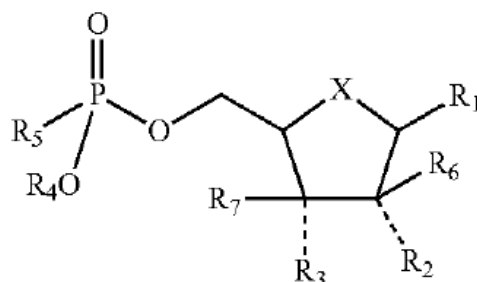
35. Hepatitis C virus infections are caused by HCV. It is estimated that more than three million Americans suffer from Hepatitis C virus infections which, over time, destroy the liver and can lead to fatal complications.

36. The '830 patent is the result of Professor Wagner's research into therapeutic nucleotide prodrugs and HINTs, including human histidine triad nucleotide-binding protein 1 (“hHINT1”).

¹ This description of the '830 patent is intended to provide a generalized explanation of the patent and technology at issue. It is not intended to be limiting and nothing herein should be construed as a legal description of the '830 patent's metes and bounds.

37. With his discovery of the role of hHINT1 in certain chemical reactions in the human body and his expertise in nucleotide analogs and prodrug chemistry, Dr. Wagner was able to invent a genus of compounds that act as antiviral agents and provide sought after antiviral treatment for, *inter alia*, HCV infections.

38. The genus of compounds Professor Wagner invented include compounds with the structural formula shown below:



wherein R₁ can be uracil, R₂ is halo (e.g., fluoro), R₆ and R₇ are independently H or (C₁-C₆) alkyl (e.g., methyl), R₃ is hydroxyl, R₄ can be aryl (e.g., a phenyl radical), R₅ is an amino acid, and X can be oxy.

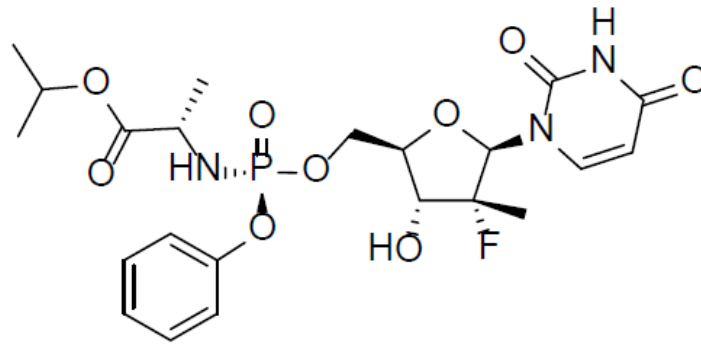
39. The importance of Dr. Wagner's contributions to the design of prodrugs of nucleotide analogs, as disclosed and claimed in the '830 patent, was widely recognized by his peers in the scientific community. Gilead's sofosbuvir medicines incorporate these contributions of Dr. Wagner.

Gilead's Infringing Drugs That Contain Sofosbuvir

40. Gilead makes and sells medicines, including Sovaldi®, Harvoni®, and Epclusa®.

41. Each of Sovaldi®, Harvoni®, and Epclusa® contains sofosbuvir, which is an antiviral agent against HCV infections.

42. Sofosbuvir has the following structural formula:



43. Sofosbuvir, whose structural formula is shown in Paragraph 42, is one of the compounds included in the genus of compounds invented by Professor Wagner and claimed in the '830 patent, as shown in Paragraph 38.

44. Sofosbuvir incorporates important and valuable technical innovations that Dr. Wagner and the University patented in the '830 patent.

45. Gilead has reaped tens of billions of dollars in sales of medicines containing sofosbuvir, including Sovaldi®, Harvoni®, and Epclusa®, without the University's authorization and without compensating the University.

COUNT I
(Infringement of the '830 Patent)

46. The allegations of the preceding paragraphs are restated and re-alleged as though fully set forth herein.

47. Gilead has infringed, and continues to infringe, literally and under the doctrine of equivalents, at least claims 1-9 and 11-12 of the '830 patent by making, using, importing, exporting, offering to sell, and/or selling medicines containing the drug sofosbuvir, including without limitation Sovaldi®, Harvoni®, and Epclusa®, because the structural formula of sofosbuvir falls within the scope of those claims.

48. Gilead has indirectly infringed, and continues to indirectly infringe, at least claims 13-21 and 23-28 of the '830 patent by actively and intentionally inducing others (including but not limited to doctors and other medical professionals) to administer medicines containing the drug sofosbuvir which infringes, literally and under the doctrine of equivalents, claims of the '830 patent.

49. Gilead has indirectly infringed, and continues to indirectly infringe, by contributing to the infringement of at least claims 13-21 and 23-28 of the '830 patent by supplying to others (including but not limited to hospitals, doctors, and other medical professionals) medicines containing the drug sofosbuvir which infringes, literally and under the doctrine of equivalents, claims of the '830 patent.

50. There are no substantial non-infringing uses of the medicines containing sofosbuvir that Gilead makes and sells.

51. Gilead knew of the '830 patent at least as early as June 11, 2015.

52. On June 11, 2015, Gilead was specifically informed of the '830 patent by the University. On July 10, 2015, Gilead was provided actual notice of Gilead's infringement of the '830 patent.

53. Additionally, in August 2015, the University met in person with Gilead to discuss Gilead's infringement of the '830 patent.

54. Notwithstanding its knowledge of the '830 patent, Gilead has continued its infringing conduct.

55. Gilead's infringement of the '830 patent was and remains willful and deliberate.

RELIEF REQUESTED

Plaintiff requests that this Court:

- A. Enter judgment that Gilead has directly and indirectly infringed the '830 patent;
- B. Award the University damages in accordance with 35 U.S.C. § 284, including all damages adequate to compensate it for Gilead's infringement, in no event less than a reasonable royalty, such damages to be determined by a jury, and additionally an accounting sufficient to adequately compensate the University, and that such damages be awarded the University, together with interest, including prejudgment and post-judgment interest, and costs;
- C. Determine that Gilead has willfully and deliberately committed acts of patent infringement, and award the University treble damages in light of Gilead's willful infringement, pursuant to 35 U.S.C. § 284;
- D. Determine that this is an "exceptional case" pursuant to 35 U.S.C. § 285 and award the University reasonable legal fees, costs, and expenses that the University incurs in prosecuting this action;
- E. Award such other and further relief as the Court deems just and proper.

JURY DEMAND

The University demands a trial by jury of all issues so triable.

Dated: August 29, 2016

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